IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	Group Art Unit: 1616
Guang-Pei CHEN et al.	Examiner: Sabiha Naim QAZI
Application No.: 10/517,874	
Filed: December 13, 2004	
For: CALCIUM SALTS OF INDOLE DERIVED STATINS	

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ada Skorodinsky, declare the following:

(1) I am a U.S. citizen and reside at 51 Winchester Road, Livingston, NJ 07039.

(2) I graduated from Moscow University with a Master of Science in Chemistry.

(3) I am a Senior Scientist with Novartis, PHAD-PDU3 (Pharmaceutical and Analytical Development-Pharmaceutical Development Unit 3)

(4) I have been employed with Sandoz – Novartis Pharmaceutical Corporation for over fifteen (15) years.

(5) I am currently responsible for physico-chemical testing of selected drug candidates, such as Polymorphism, Properties in Solution, Screening New Forms and Form Selection studies.

(6) I have read and am familiar with the above identified United States patent application, i.e., U.S. Ser. No. 10/517,874, filed December 13, 2004, as well as the Amendment to be filed contemporaneously with this Declaration.

(7) The following relevant experiments were conducted by me or under my direct supervision.

EXPERIMENTS

Introduction:

The sodium salt of fluvastatin, isolated as fibrous crystals, is a very hygroscopic slightly yellow semi-crystalline powder. The calcium salt crystallizes as small white needles.

Procedure:

About 13 mg each of powder calcium salt of fluvastatin and the powder sodium salt of the same compound were dried at 0% RH (Relative Humidity) and measured at an RH value of 84% on a humidity microbalance (DVS from Surface Measurement Systems). The sample temperature throughout the experiment was approximately 23°C and the criterion for RH change (moisture gain) was dm/dt of < 0.002% (dm/dt: change in weight of a sample over time at a given relative humidity).

Results:

The sodium salt of fluvastatin showed 26.0% gain at 84%RH, whereas the calcium salt of the same compound showed only 2.8% gain at 84%RH. Importantly, it was thereby determined unexpectedly that the calcium salt is *significantly* less hygroscopic than the sodium salt.

Conclusion:

The calcium salt of fluvastatin is considerably less hygroscopic than the sodium salt, i.e., 2.8% gain at 84%RH vs. 26.0% gain at 84%RH, respectively.

I further declare that all statements made herein of my own knowledge are true and that all statements on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

Date: March 17, 2008 Ada Skorodinsky

Ada Skorodinsky